

May 13, 1999¹⁵⁸⁹ '99 MAY 20 AMO 36

Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, M.D. 20857

Dear Sir or Madam:

This is being sent to let you know that I do not support restricting the availability of individually compounded medication, and I oppose the Draft M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medication by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

My OB/GYN, in Kentucky, placed me on the natural progesterone wafer three years ago due to excessive bleeding. The only way I can obtain the medication is to order it from Madison Pharmacy in Wisconsin. The medication has helped eliminate the problem, which helps protect my body from more serious health problems. The quality of my life is greatly improved by the use of this medication.

Please do Not vote to restrict my ability to obtain this needed medication. This hormone, in the natural form that I can only obtain through the mail, has much fewer side-effects than the synthetic form. My OB/GYN, who is very respected in his field, highly recommends this medication, over the synthetic form, for my particular gynecological problems. The services that this speciality pharmacy provides to me and my doctor, and many other patients, are not available from commercial pharmaceutical manufacturers, nor through most local pharmacies.

I greatly appreciate your attention to my concerns about a matter that could greatly affect my ability to receive what my physician feels is the best treatment for my health problems.

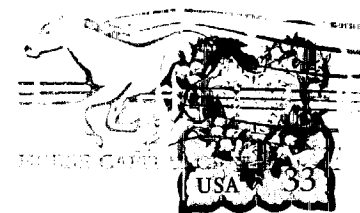
Sincerely,

Sheree Combs
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